RD2007-11

Registration Decision

UCARCIDE 250 Antimicrobial Glutaraldehyde

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Registration Decision for Glutaraldehyde

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, and in accordance with the Pest Control Products Regulations, is granting full registration for the sale and use of UCARCIDE 250 Antimicrobial and GLUTEX GQ1 Sanitizer, containing the technical grade active ingredient glutaraldehyde, for use in reducing the levels of microorganisms on hard surfaces found in animal production facilities and on farm equipment. These include poultry and turkey houses, swine housing and farrowing areas, barns and large animal buildings, hatchers, setters, chick processing facilities, cages, and vehicles used to transport animals.

Current scientific data from the registrant and scientific reports were evaluated to determine if, under the proposed conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the Consultation Document[1] *Proposed Registration Decision—UCARCIDE 250 Antimicrobial Glutaraldehyde* (PRD2007-09). This Registration Decision[2] describes this stage of the PMRA's regulatory process for UCARCIDE 250 Antimicrobial and summarizes the Agency's decision, the reasons for it and provides, in Appendix I, a summary of comments received during the consultation process as well as the PMRA's response to these comments. This decision is consistent with the proposed registration decision stated in *Proposed Registration Decision—UCARCIDE 250 Antimicrobial Glutaraldehyde* (PRD2007-09).

For more details on the information presented in this Registration Decision, please refer to the PRD2007-09 *Proposed Registration Decision—UCARCIDE 250 Antimicrobial Glutaraldehyde*, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act.*

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act.*

generations or the environment will result from use or exposure to the product under its conditions of registration.[3] The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies hazard and risk assessment methods as well as policies that are rigorous and modern. These methods consider the unique characteristics of sensitive subpopulations in both humans (e.g. children) and organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides and on the assessment process and risk-reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

What is Glutaraldehyde?

Glutaraldehyde is an antimicrobial that inhibits the growth of microorganisms (e.g. bacteria, fungi and viruses) through the alteration of RNA, DNA and protein synthesis.

Health Considerations

Can Approved Uses of Glutaraldehyde Affect Human Health?

Glutaraldehyde is unlikely to affect your health when used according to label directions.

People could be exposed to glutaraldehyde when handling and applying the product. When assessing health risks, the PMRA considers two key factors: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers).

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose at which no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when products containing glutaraldehyde are used according to label directions.

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3 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act.*

4 "Value" as defined by subsection 2(1) of the *Pest Control Products Act* is "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

UCARCIDE 250 Antimicrobial and GLUTEX GQ1 Sanitizer caused moderate to high acute toxicity in laboratory animals, were corrosive to the eyes and skin of rabbits and are considered to be potential dermal and respiratory sensitizers. Consequently, the statements "Danger Poison", "Corrosive to eyes and skin" and "Potential skin and respiratory tract sensitizer" are required on the labels for both products.

Glutaraldehyde did not cause cancer or affect the nervous system in animals. When glutaraldehyde was given to pregnant animals, effects on the developing fetus were observed at doses that were toxic to the mother, indicating that the fetus is not more sensitive to glutaraldehyde than the adult animal. Health effects in animals given daily doses of glutaraldehyde over long periods of time included effects on the kidney and irritation at the site of first contact as well as death at very high doses. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests. Only those uses where exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Residues in Water and Food

The uses of glutaraldehyde associated with the end-use product GLUTEX GQ1 Sanitizer do not involve application to food.

Risk in Residential and Other Non-Occupational Environments

Estimated risk for non-occupational exposure is not of concern. This is a commercial product.

Workplace Risks From Handling GLUTEX GQ1 Sanitizer

Occupational risks are not of concern when GLUTEX GQ1 Sanitizer is used according to the proposed label directions, which include protective measures.

A risk assessment conducted for individuals handling and re-entering areas treated with GLUTEX GQ1 Sanitizer indicated that risk for adults is not of concern when the product is used according to label directions.

Farmers and pesticide applicators mixing, loading and applying GLUTEX GQ1 Sanitizer can come in direct contact with GLUTEX GQ1 Sanitizer on the skin or through inhalation. Therefore, the label will specify that anyone mixing or loading GLUTEX GQ1 Sanitizer must wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, socks and chemical-resistant footwear, eye protection and a NIOSH-approved organic-vapour-removing cartridge with a prefilter respirator during mixing, loading, application, clean-up and repair.

Environmental Considerations

What Happens When Glutaraldehyde is Introduced Into the Environment?

The end-use product containing glutaraldehyde will be used only on indoor surfaces; therefore, entry of glutaraldehyde into the environment is expected to be negligible.

Value Considerations

What Is the Value of Glutex GQ1 Sanitizer?

GLUTEX GQ1 is a sanitizer for non-food contact surfaces found in animal production facilities and farm equipment. These include poultry and turkey houses, swine housing and farrowing areas, barns and large animal buildings, hatchers, setters, chick processing facilities, cages, and vehicles used to transport animals.

GLUTEX GQ1 Sanitizer offers a different chemistry over other types of sanitizers to help reduce the levels of bacterial, fungal and viral pathogens that can have potentially devastating effects in animal production facilities. GLUTEX GQ1 Sanitizer is not intended for use on food or feed, or on premises where food is prepared, manufactured or kept.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of GLUTEX GQ1 Sanitizer to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

- **Human Health**

Because there is a concern with users coming into direct contact with GLUTEX GQ1 Sanitizer on the skin or through inhalation, anyone mixing or loading GLUTEX GQ1 Sanitizer must wear coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, socks and chemical-resistant footwear, eye protection and a NIOSH-approved organic-vapour-removing cartridge with a prefilter respirator during mixing, loading, application, clean-up and repair.

Persons re-entering areas treated with GLUTEX GQ1 Sanitizer could be exposed to glutaraldehyde through inhalation; therefore, treated areas must be ventilated prior to re-entry. The label also refers to occupational exposure limits established for glutaraldehyde.

Other Information

1. The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

2. Any person may file a notice of objection[5] regarding this registration decision within 60 days of the date of publication of this Registration Decision Document. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

[5] As per subsection 35(1) of the *Pest Control Products Act*.

List of References

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

3.0 Impact on Human and Animal Health

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PMRA 1173771 — AQUCAR 514 acute inhalation toxicity study. Bushy Run Research Center. Study number: 48-3. Study report date: March 4, 1985. DACO 4.6.3.

PMRA 1218862 — Skin Penetration and Pharmacokinetics of Glutaraldehyde in Rats and Rabbits. Bushy Run Research Center. Study number: 47-197. Study report date: January 15, 1985. DACO 4.5.9.

PMRA 1158493 — Anuskiewicz, C.M., Ballantyne, B., Garman, R.H., McKelvey, J.A., Tallant, M.J. (1992). Percutaneous pharmacokinetics and material balance studies with glutaraldehyde. J. Toxciol.-Cut. & Ocular Toxicol., 11(4), 341-367. DACO 4.5.9.

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PMRA 1158496 — UCARCIDE Antimicrobial 250: Acute peroral toxicity study in the rat. Bushy Run Research Center. Study number 54-145. Study report date: January 9, 1992. DACO 4.2.1.

PMRA 1218836 — Glutaraldehyde dilutions: Percutaneous toxicity and eye irritation studies. Bushy Run Research Center. Study number: 44-65. Study report date: June 1, 1981. DACO 4.2.2, 4.2.4.

PMRA 1218841 — Glutaraldehyde dilutions (45%, 15%, 10%): Acute percutaneous studies. Bushy Run Research Center. Study number: 48-51. Study report date: June 10, 1985. DACO 4.2.2.

PMRA 1173340 — Glutaraldehyde: Acute vapor inhalation toxicity study in rats. Bushy Run Research Center. Study number 93U1256. Study report date: June 29, 1995. DACO 4.2.3.

PMRA 1218843 — Glutaraldehyde: Four hour LC50 inhalation study on rats. Bushy Run Research Center. Study number: 44-96. Study report date: January 7, 1982. DACO 4.2.3.

PMRA 1218845 Glutaraldehyde: Acute inhalation toxicity with chamber analysis. Bushy Run Research Center. Study number: 47-21. Study report date: February 28, 1984. DACO 4.2.3.

PMRA 1147991 UCARCIDE Antimicrobial 250: Acute vapor inhalation toxicity test in rats. Study number: 53-8. Study report date: November 6, 1990. DACO 4.2.3.

PMRA 1218848 Glutaraldehyde dilutions: Primary skin and eye irritancy studies. Bushy Run Research Center. Study number 47-33. Study report date: November 14, 1984. DACO 4.2.4.

PMRA 1158494 Mouse lymph node assay and mouse IgE test on glutaraldehyde. Zeneca. Study number IK/VMC/a0085. Study report date: July 22, 1994. DACO 4.2.6.

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PMRA 1218838 Evaluation of the subacute dermal toxicity of glutaraldehyde in mice. Bushy Run Research Center. Study number: 44-107. Study report date: December 7, 1981. DACO 4.3.5.

PMRA 1147993 Glutaraldehyde: Twenty-eight day repeated cutaneous dose toxicity study in Fischer 344 rats. Bushy Run Research Center. Study number: 93U1252. Study report date: May 26, 1994. DACO 4.3.5.

PMRA 1218854 Glutaraldehyde vapor nine-day inhalation study on rats. Bushy Run Research Center. Study number: 46-95. Study report date: November 8, 1983. DACO 4.3.6.

PMRA 1218856 Glutaraldehyde vapor subchronic inhalation study on rats. Bushy Run Research Center. Study number: 46-101. Study report date: December 15, 1983. DACO 4.3.6. Volume 1 of 2.

PMRA 1218860 Glutaraldehyde vapor subchronic inhalation study on rats. Bushy Run Research Center. Study number: 46-101. Study report date: December 15, 1983. DACO 4.3.6. Volume 2 of 2.

PMRA 1158499 Subchronic inhalation studies on glutaraldehyde to F344/N rats and B6C3F1 mice. National Toxicology Program. NTP Toxicity Report No. 25. Study report date: March 1993. DACO 4.3.6.

PMRA 1158492 Gross, E.A., Mellick, P.W., Kari, F.W., Miller, F.J., and Morgan, K.T. (1994) Histopathology and cell replication responses in the respiratory tract of rats and mice exposed by inhalation to glutaraldehyde for up to 13 weeks. Fundamental and Applied Toxicology, 23: 348-362. DACO 4.3.6.

PMRA 1142317 13-week toxicity study in dogs with administration via the drinking water. Bushy Run Research Center & Hazleton Laboratories. Study number: 52-93. Study report date: January 29, 1990. DACO 4.3.8.

PMRA 1109824 NTP technical report on the toxicology and carcinogenesis studies of glutaraldehyde (CAS No. 111-30-8) in F344/N rats and B6C3F1 mice (inhalation studies). National Toxicology Program. NTP Toxicity Report No. 490. Study report date: September 1999. DACO 4.4.2, 4.4.3.

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PMRA 1147995 Glutaraldehyde: Combined chronic toxicity/oncogenicity study in the drinking water of rats. Bushy Run Research Center. Study number: 91U0012. Study report date: March 18, 1994. DACO 4.4.4. Volume 2 of 2.

PMRA 1147997 Glutaraldehyde: Two-generation reproduction study in the drinking water of CD rats. Bushy Run Research Center. Study number: 92UI059. Study report date: March 24, 1994. DACO 4.5.1.

PMRA 1131531 Study of the prenatal toxicity of glutaraldehyde in rats after oral administration (drinking water). BASF Department of Toxicology. Study number: 33R0599/89025. Study report date: February 11, 1991. DACO 4.5.2.

PMRA 1131530 Study of the prenatal toxicity of glutaraldehyde in rabbits after oral administration (gavage). BASF Department of Toxicology. Study number: 40R0599/89026. Study report date: February 11, 1991. DACO 4.5.3.

PMRA 1148031 UCARCIDE Antimicrobial 250 (Glutaraldehyde, 50% aqueous solution): Mutagenic potential in the Salmonella/microsome (Ames) assay. Bushy Run Research Center. Study number: 92U1178. Study report date: September 15, 1993. DACO 4.5.4.

PMRA 1218909 Glutaraldehyde: Salmonella/microsome (Ames) bacterial mutagenicity assay. Bushy Run Research Center. Study number: 44-131. Study report date: December 11, 1981. DACO 4.5.4.

PMRA 1201048 Glutaraldehyde 50%: In vitro mutagenesis studies - 3 battery test. Chemical Hygiene Fellowship, Carnegie-Mellon Institute of Research. Study number: 43-16. Study report date: January 28, 1980. DACO 4.5.5, 4.5.6, 4.5.8.

PMRA 1148022 UCARCIDE Antimicrobial 250 (Glutaraldehyde, 50% aqueous solution): Mutagenic potential in the CHO/HGPRT forward mutation assay. Bushy Run Research Center. Study number: 92U1179. Study report date: April 8, 1994. DACO 4.5.5.

PMRA 1148011 UCARCIDE Antimicrobial 250 (Glutaraldehyde 50% aqueous solution): Sister chromatid exchange assay in cultured CHO cells. Bushy Run Research Center. Study number: 92U1180. Study report date: April 7, 1994. DACO 4.5.6.

PMRA 1148029 UCARCIDE Antimicrobial 250 (Glutaraldehyde, 50% aqueous solution): In vitro chromosomal aberration assay in Chinese hamster ovary cells. Bushy Run Research Center. Study number: 54-101. Study report date: September 12, 1991. DACO 4.5.6.

PMRA 1148030 UCARCIDE Antimicrobial 250 (Glutaraldehyde, 50% aqueous solution): In vivo peripheral blood micronucleus test with Swiss-Webster mice. Bushy Run Research Center. Study number: 91U0101. Study report date: February 26, 1993. DACO 4.5.7.

PMRA 1148032 UCARCIDE Antimicrobial 250 (Glutaraldehyde, 50% aqueous solution): Bone marrow chromosomal aberration assay in rats. Bushy Run Research Center. Study number 91U0139. Study report date: May 27, 1993. DACO 4.5.7.

PMRA 1280150 Duration of eye irrigation for corrosive materials: at least 30 minutes. Dow AgroSciences. Study report date: March 4, 2003. DACO 4.8.

PMRA 880884 Azadi, S., Klink, K.J., Meade, B.J. (2004). Divergent Immunological Responses Following Glutaraldehyde Exposure. Toxicology and Applied Pharmacology, 197:1-8. DACO 4.6.6.

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5.0 Value

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PMRA 875638	Health and Live Production Practices in the Commercial Poultry Industry: Sanitation Programs and Their Significance in Poultry and Livestock - Selected Target Organisms, An Overview. Auburn University, DACO: 10.2.2,10.4.
PMRA 875639	1999, Virucidal Effectiveness Test for UCARSAN 414 Sanitizer, MicroBioTest, Inc., 374-106, DACO: 10.2.3.2.
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PMRA 875642	Use of Glutaraldehyde-Based Products in Egg Sanitization for Hatching Egg Treatments; 38 pgs., Union Carbide Corporation, DACO: 10.2.3.3.
PMRA 875643	Efficacy of Sanitizer 3134 (SLN# MS 990004) as a Sanitizer in Chicken Hatcheries in the State of Mississippi; 31 pgs., Union Carbide Corporation, DACO: 10.2.3.3.
PMRA 875644	Glutaraldehyde Containing Products - Resistance Management; 29 pgs., Dow Chemical Canada, Inc., DACO: 10.5.3.
PMRA 1280151	2006, Virucidal Evaluation of UCARCIDE 250 Antimicrobial, UCARSAN Sanitizer 420, UCARSAN 414 Sanitizer and GX + 10% Low Foam (G-cide) For use on Inanimate Environmental Surfaces: Test for Efficacy Against Highly Pathogenic Avian Influenza Virus. DACO: 0.8.11, 10.2.
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PMRA 1280156	2005, Virucidal Efficacy Test Glutaraldehyde-Based Products SARS-associated Coronavirus;, MICROBIOTEST, 510-104, MRID: 46818103 and 46805003, DACO: 10.2.

B. ADDITIONAL INFORMATION CONSIDERED

i) Published Information

3.0 Impact on Human and Animal Health

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Appendix I Comments and Responses

1. A comment on the terminology used in the French version of *Proposed Registration Decision—UCARCIDE 250 Antimicrobial Glutaraldehyde* (PRD2007-09) was received. The comment indicated that the word "assainisseur" is a more accurate translation of the English word "sanitizer".

   Response

   The PMRA agrees that the term "assainisseur" is more appropriate than "désinfectant" in the translation of "sanitizer." The required changes are reflected in the French version of the Registration Decision document.